

Lornoxicam versus tramadol for post-operative pain relief in patients undergoing ENT procedures

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ABSTRACT

Background: Pain following ear-nose and throat surgery is one of the most important complaints for which, several drugs are used. This prospective, randomized, double-blind controlled trial was designed to compare the analgesic effect of tramadol versus lornoxicam for post-operative pain relief in patients undergoing ENT surgical procedures. **Methods:** One hundred and twenty patients of ASA class I-II, who had undergone elective ENT surgical procedures under general anesthesia, were assigned in a randomized manner into three equal groups. Group L received lornoxicam 8 mg IV, Group T received tramadol 1 mg/kg IV and Group C received IV saline after induction of anesthesia before the start of the surgery. Post-operative pain was assessed using the visual analogue scale (VAS) and sedation level was evaluated during stay in the post-anesthesia care unit with a four-point sedation scale. Intraoperative blood loss was estimated using the Five-Point Scale. Adverse events in the first 24 h post-operative were recorded. **Results:** The VAS pain scores were significantly higher in Group C as compared with those in Groups L and T at 30 min and 1, 2, 4 and 6 h post-operatively, with no significant difference between Group L and Group T. The amount of morphine consumption post-operatively was significantly lower in Group L (5.2 ± 2.5 mg) and Group T (5.0 ± 2.0 mg) as compared with that in Group C (7.4 ± 2.3 mg) ($P = 0.001$). The time for the first analgesic requirement was significantly less in Group L (92.62 ± 24.23 min) and Group T (88 ± 21.43 min) as compared with that in Group C (42.82 ± 25.61 min), with no significant difference between the other two groups. Estimated intraoperative blood loss score by the surgeons showed no significant difference between the three groups. The most frequent side-effects in the three groups were nausea and vomiting, and their incidence was significantly higher in the placebo group as compared with the other two groups. **Conclusion:** Tramadol 1 mg/kg was comparable to lornoxicam 8 mg for post-operative pain relief in patients undergoing ENT surgical procedures; both drugs helped to reduce the post-operative opioid requirement and consequently minimized the related adverse effects of the opioids.

Key words: ENT procedures, lornoxicam, post-operative pain relief, tramadol

INTRODUCTION

Post-operative pain is a significant problem and has several unwanted consequences, such as excessive use of analgesics, longer period of hospitalization, intolerance to diet and subsequently poorer quality of life.^[1] Although the systemic administration of opioids is traditionally used

in the treatment of post-operative pain, their potential side-effects such as respiratory depression, sedation, ileus, urinary retention and itching, limit their administration particularly following a surgical procedure involving the upper respiratory pathway.^[2] Numerous studies have shown pre-emptive analgesia to be effective in perioperative pain.^[3,4] Non-steroid anti-inflammatory drugs (NSAIDs) found a widespread use as effective post-operative analgesic regimen with fewer adverse effects.^[5-7]

NSAIDs have analgesic effects due to their peripheral anti-inflammatory actions by reducing the synthesis of prostaglandins through the inactivation of cyclooxygenase. This peripheral action of the NSAIDs can thus indirectly inhibit central neural sensitization and reduce the amplification of pain.^[8,9] Lornoxicam (Xefo) is a

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10.4103/1658-354X.125935

non-selective NSAID of the oxicam group, a potent analgesic with anti-inflammatory properties, which decreases prostaglandin synthesis by inhibition of cyclooxygenase. It is rapidly eliminated with a plasma elimination half-life of 3-5 h, and this short plasma half-life may be responsible for lornoxicam's reduced incidence of adverse effects.^[6]

Lornoxicam has been successfully used in the prevention and treatment of post-operative pain.^[3,5,7-14] Tramadol is a synthetic, centrally acting analgesic agent that is structurally related to codeine and morphine. It is a weak μ -opioid receptor agonist and it also induces analgesia by inhibiting monoamine reuptake, specifically serotonin and norepinephrine, at synapses in the descending inhibitory pain pathways.^[15] It has a plasma half-life of approximately 6-7 h.^[16]

Its potency is weaker than morphine, but it has a lower risk of dependency and respiratory depression. However, it has some side-effects such as nausea, vomiting, sweating, dizziness and lowering the seizure threshold.^[15,16] Numerous studies have confirmed the efficacy of tramadol in the management of perioperative pain.^[17-20] Therefore, the aim of this study was to compare the analgesic effect of tramadol and lornoxicam for post-operative pain relief in patients undergoing ENT surgical procedures.

METHODS

After obtaining ethical committee approval and an informed written consent, 120 ASA physical status I-II healthy adult patients aged 18-45 years, of both sexes, scheduled for elective ENT surgical procedures, were included in this prospective, randomized, double-blind, comparative study between May 2012 and March 2013. Patients with known hypersensitivity to medication drugs, coagulation disorders, bronchial asthma, pregnancy, lactation, significant cardiac, kidney or liver dysfunction, peptic ulcer, alcohol abuse, active bleeding for any cause and patients receiving any analgesic medications within 24 h pre-operative or antiplatelet medication within the past 2 weeks were excluded from the study.

All patients were submitted to the routine pre-operative evaluation and laboratory studies according to the hospital's standard. Visual analogue scales (VAS) were explained to the patients during the pre-operative visit. All patients were fasted overnight and received midazolam 0.05 mg/kg and ranitidine 150 mg orally as a pre-anesthetic medication 2 h before the operation.

Patients were randomly allocated into three equal groups using a computer-generated randomization scheme to

receive 8 mg lornoxicam (Group L) (XefoR) IV or tramadol (Group T) (ContramalR) 1 mg/kg IV or saline (Group C) after induction of anesthesia before the start of the surgery. On arrival to the operative theater, standardized monitoring techniques including electrocardiogram (ECG), pulse oximetry (SpO₂) and capnography, non-invasive blood pressure monitoring, body temperature and neuromuscular transmission (TOF; transmission with four stimulators) were applied.

All patients received a standardized anesthetic technique that included induction with propofol 2-3 mg/kg IV, fentanyl 2 μ g/kg IV and cisatracurium (0.15 mg/kg) IV to facilitate tracheal intubation. Anesthesia was maintained with 50% oxygen in air and 1.5-2% sevoflurane. Neuromuscular blockade was maintained by administering intermittent boluses of cisatracurium if needed. Patients were mechanically ventilated in ventilation parameters that maintain an end-tidal carbon dioxide tension at 35-40 mmHg.

After induction of anesthesia before the start of the surgery, patients in Group L received 8 mg lornoxicam intravenously diluted to 10 mL, patients in Group T received 1 mg/kg IV tramadol intravenously diluted to 10 mL and patients in Group C received 10 mL of normal saline IV. The study medications were prepared, covered and coded by an independent observer who was not participating in any other part of the study and the study drugs were administered by an anesthesiologist who was not involved in the management of anesthesia or follow-up period to maintain the double-blind nature of the study. The attending anesthesiologist, surgeon and data collection personnel were blinded to the patient group assignment and to the nature of the study medication.

All patients in all groups received a strict fluid replacement according to the standard fluid administration guidelines during anesthesia. During surgery, all surgeons used a standardized protocol of local anesthetic administration to infiltrate the operative site by 1% lidocaine with epinephrine (1:100,000) for bleeding and pain control. An increase in blood pressure or heart rate by more than 15% from the pre-operative value was defined as insufficient analgesia and was treated with intermittent doses of fentanyl 0.5 μ g/kg IV if needed. No other sedatives or opioid were administered during operation. Dexamethasone 0.2 mg/kg IV (maximum 16 mg) was administered for the control of post-operative nausea and vomiting. All the procedures were performed by the same three surgeons, all with a clinical experience of more than 5 years using the same surgical technique for each type of surgery.

At the end of the surgery, anesthesia was discontinued and 100% oxygen was administered. The oral cavity was inspected under direct vision and then the secretions and blood clots were aspirated. The residual neuromuscular relaxation was reversed using neostigmine 40 ug/kg and atropine 20 ug/kg slowly by the intravenous route. Extubation was performed awake after the return of protective airway reflexes.

Intraoperative blood loss was estimated roughly by surgeons by visual estimation of the blood volume lost in suction bottles and swab counting using the Five-Point Scale (0 = no bleeding, 1 = bleeding as usual, 2 = bleeding more than usual, 3 = profuse, 4 = excessive and, lastly, 5 = excessive and continuously).^[12]

An anesthesiologist who was blinded to the patient's group allocation recorded recovery times including time to spontaneous eye opening in response to a verbal command and time to orientation at 1-min intervals after discontinuation of the anesthetics. Patients were transported to the post-anesthesia care unit (PACU) and the nurse who was blinded to the patients' group allocation continued the patient observation. The time at which the patients attained an Aldrete score >9 ^[21] was noted and all the patients stayed for at least 60 min observation in the PACU independent of whether or not they gained discharge criteria earlier.

The pain intensity score was assessed post-operatively by using VASs, marking on a continuous line of 10 cm, with 0 = no pain and 10 = intolerable pain. VAS assessments were performed at rest at the following time points: at 30 min and 1, 2, 4, 6, 12 and 24 h post-operatively. Neither the patient nor the observer knew which study drug was administered.

Rescue analgesia with 2 mg bolus doses of morphine (injected at 10-min intervals) was given intravenously if requested and if the VAS scores were ≥ 3 for a maximum dose of 10 mg until adequate pain relief was achieved. Paracetamol 15 mg/kg was the second rescue analgesic if the VAS scores were ≥ 3 in spite of IV morphine, and was repeated every 4 h if needed because paracetamol is the standard post-operative pain medication for patients undergoing the ENT surgical procedure in our hospital. Time for first post-operative analgesic, which is the time elapsed between end of surgery and first administration of an analgesic, was noted.

In addition, the total consumption of rescue analgesics in the first 24 h post-operatively was calculated. Sedation level was evaluated during the PACU stay with a Four-Point Sedation Scale (0 = eyes open spontaneously, 1 = eyes open

to speech, 2 = eyes open when shaken and 3 = unrousable^[22] at arrival to the PACU) at 30 min, 1 and 2 h by a nurse who was not aware of the study drug used. Adverse events in the first 24 h post-operative were treated and recorded for each patient, including respiratory depression (respiratory rate ≤ 10), desaturation ($SpO_2 \leq 92\%$), nausea, vomiting, bleeding, allergic reactions, urinary retention and any abnormal gastrointestinal manifestations. Ondansetron 4 mg was administered by intravenous route as a rescue antiemetic.

Statistical Analysis

A priori power analysis was performed on the basis of the mean post-operative morphine consumption data obtained from a pilot study on 15 patients receiving placebo (five cases of tonsillectomy, five cases of septoplasty and five cases of septorhinoplasty; all cases were not allocated in the study). A sample size of 40 patients per study group was estimated to have at least an 80% power ($\alpha = 0.05$) to detect a 50% reduction in the total post-operative morphine consumption. Analysis was performed using SPSS version 17 (Chicago, IL, USA). Numerical data were expressed as mean \pm SD, numbers and percentages. Analysis of variances (ANOVAs) followed by Tukey posthoc test were used for the comparison of parametric data. The Kruskal-Wallis test was used to compare non-parametric data (when indicated). Categorical data were compared using the Chi square test. A *P*-value of 0.05 was used as the level of significance.

RESULTS

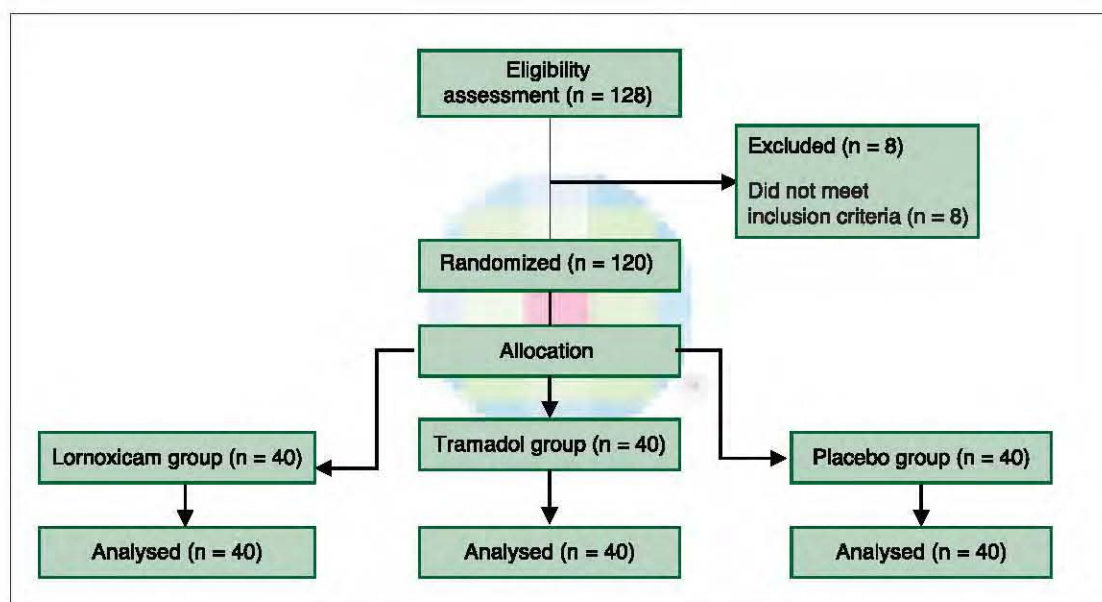
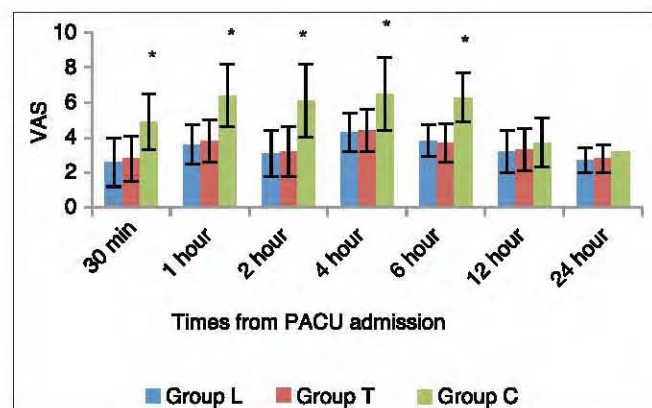
One hundred twenty-eight patients were screened for eligibility to participate in this study and 120 patients subsequently consented and were enrolled in the study ($n = 40$ per group), with no patient drop-outs [Figure 1]. There were no significant differences among the three groups with respect to age, gender, weight, ASA class, duration of surgery and anesthesia ($P > 0.05$) [Table 1].

The VAS pain scores were significantly higher in Group C as compared with those in Groups L and T at 30 min and at 1, 2, 4 and 6 h post-operatively ($P < 0.05$), with no significant difference in the pain score between Group L and Group T ($P > 0.05$) [Figure 2]. The time for the first analgesic requirement was significantly longer in Group L (92.62 ± 24.23 min) and Group T (88 ± 21.43 min) as compared with that in Group C (42.82 ± 25.61 min) ($P = 0.011$), with no difference between Group L and Group T ($P > 0.05$) [Table 2]. The amount of morphine consumption post-operatively was significantly lower in Group L (5.2 ± 2.5 mg) and Group T (5.0 ± 2.0 mg) as compared with that

Table 1: Demographic characteristics

	Group L	Group T	Group C	P
Number (n)	40	40	40	
Age (years)	27.47±8.61	26.30±7.24	28.92±9.83	0.332
Weight (kg)	69.69±12.61	70.26±14.24	68.92±11.93	0.413
Sex (M/F)	17/23	16/24	16/24	0.394
ASA physical status I/II	26/14	26/14	25/15	0.662
Duration of anesthesia (min)	102.18±20.42	104.57±19.34	106.01±22.60	0.321
Duration of surgery (min)	114.26±16.93	111.68±15.37	113.72±14.61	0.450
Type of surgery				
Tonsillectomy	12(30)	11(27.5)	11(27.5)	0.821
Septoplasty	16(40)	17(42.5)	16(40)	0.756
Septorhinoplasty	12(30)	12(30)	13(32.5)	0.723

Values are presented as mean±SD, number (%) and percentages; ASA: American Society of Anesthesiologists (physical status).

**Figure 1:** Flow chart of the study**Figure 2:** Visual analog scale (VAS) of the studied groups. Data are presented as mean±SD. *Significantly different compared with the other two groups ($P < 0.05$)

in Group C (7.4 ± 2.3 mg) ($P = 0.001$), with no statistical difference between Group L and Group T ($P > 0.05$) [Table 2].

The number of patients requiring morphine was significantly higher in Group C compared with the other two groups ($P = 0.016$), with no statistical difference between Group L and Group T ($P > 0.05$) [Table 2]. The most frequent side-effects in the three groups were nausea and vomiting, and their incidence was significantly higher in Group C as compared with the other two groups ($P = 0.002$) [Table 2]. There is no significant difference between the three groups regarding recovery times or the mean sedation scores in PACU ($P > 0.05$) [Table 2]. The estimated intraoperative blood loss score by the surgeons showed no significant difference between the three groups

($P > 0.05$) [Table 3]. Prolonged excessive post-operative bleeding requiring surgical intervention was not observed in any patient

DISCUSSION

In this prospective, randomized, double-blind, placebo-controlled study, the analgesic effect of both lornoxicam 8 mg IV and tramadol 1 mg/kg IV administered after induction of anesthesia was comparable and clinically evident by lower pain scores in the first 6 h, prolonged time to first analgesic request and reduced post-operative narcotic analgesic consumption (morphine) for patients undergoing ENT surgical procedures. Several clinical trials have established the pre-emptive analgesic effects at a dose of 8 mg for lornoxicam.^[7,10]

Lornoxicam 8 mg IV was found to be superior to placebo and equianalgesic to tramadol 50 mg IV in relieving moderate to intolerable post-hysterectomy pain.^[8] Işık *et al.*^[10] found that pre-operative 8 mg lornoxicam was more effective than 50 mg tramadol with respect to early post-operative tonsillectomy pain in adult patients, and the

side-effects profile was similar. Staunstrup *et al.*^[20] compared the analgesic efficacy of a single dose of intramuscular lornoxicam 16 mg and tramadol 100 mg in 76 patients following arthroscopic reconstruction of the anterior cruciate ligament and found that lornoxicam is alternative to tramadol for the treatment of moderate to severe pain. However, the discrepancy between studies could be due to different doses of tramadol and lornoxicam and also because of the different types of surgical procedures.

There are numerous studies in the literature where different doses of lornoxicam and tramadol have been used in post-operative pain treatment in various types of surgical procedures. Sener and colleagues^[5] in their study on 200 patients scheduled for elective septoplasty under general anesthesia reported that lornoxicam 8 mg (twice daily) was effective for post-operative analgesia and reduction of opioid requirement. Another study^[13] revealed the efficacy and better tolerability of IV lornoxicam in patient-controlled analgesia for post-operative pain relief after septorhinoplasty. Daabiss *et al.*^[14] reported that lornoxicam 16 mg is comparable to fentanyl as intraoperative IV analgesia and that it is associated with a significantly lower incidence

Table 2: Recovery parameters and post-operative data

	Group L	Group T	Group C	P
Time to spontaneous eye opening(min)	5.10±2.61	4.88±3.23	4.92±2.84	0.752
Time to orientation (min)	9.22±2.70	9.14±1.72	8.90±2.62	0.841
Time to an Aldrete score >9	23.53±6.72	24.15±5.80	23.17±6.13	0.723
Intraoperative fentanyl consumption (ug/kg)	2.76±0.38	2.84±0.42	2.72±0.35	0.820
Time to first request of rescue analgesic(min)	92.62±24.23	88±21.43	42.82±25.61*	0.011
Total morphine consumption (mg)	5.2±2.5	5.0±2.0	7.4±2.3*	0.001
Morphinen (%)	5(12.5)	8(20)	15(37.5)*	0.016
Total paracetamol consumption (mg)	2346±185	2403±204	3600±312*	0.042
Post-operative sedation score	1.7±0.6	1.8±1.2	1.6±0.8	0.673
Post-operative nausea/vomiting (n)	8/5	9/6	15/11*	0.002
Rescue antiemetic n(%)	6(15)	7(17.5)	12(30)*	0.004

Values are presented as mean±SD and number of patients (n) or percentages (%). *Significantly different compared with the other two groups ($P < 0.05$).

Table 3: Intraoperative blood loss as estimated by the surgeon

	Group L	Group T	Group C	P
Intraoperative bleeding score				
No bleeding	4(10)	3(7.5)	3(7.5)	0.520
Bleeding as usual	28(70)	30(75)	29(72.5)	0.456
Bleeding more than usual	8(20)	7(17.5)	8(20)	0.378
Profuse	0(0)	0(0)	0(0)	—
Excessive	0(0)	0(0)	0(0)	—
Excessive and continuous	0(0)	0(0)	0(0)	—
Intraoperative blood loss (mL)	99.85±38.62	100.56±36.01	103.45±30.98	0.548

Data are presented as mean±SD, number (n) and percentages (%).

of adverse events, but is more effective than fentanyl in preventing early post-operative pain in patients undergoing minor to moderate day-case ENT surgical procedures.

Trampitsch *et al.*^[3] have investigated the effect of administration of lornoxicam pre-emptively in patients undergoing gynecological operation and have reported better quality of post-operative analgesia and reduced consumption of opioid analgesics. Similar results have been obtained when 16 mg of lornoxicam was administered after thyroidectomy, where the time needed for the first analgesic requirement was prolonged with decreased opioid requirements.^[9]

The use of NSAIDs for post-operative pain relief is controversial, particularly in tonsillectomy, because NSAIDs are claimed to increase the risk of perioperative bleeding caused by inhibition of platelet function by inhibiting cyclooxygenase and consequently inhibiting thrombocyte aggregation^[6] Blaicher *et al.*^[23] compared the effect of rofecoxib (a selective NSAID) and three non-selective NSAIDs: acetylsalicylic acid, diclofenac, and lornoxicam, on platelet function and they reported that platelet function was significantly inhibited by acetylsalicylic acid, diclofenac and lornoxicam but not by rofecoxib.

As platelets play an important role in the coagulation process, some authors believe that NSAIDs should be avoided during surgical procedures like tonsillectomy^[24] while other authors reported that NSAIDs are a useful analgesic for post-operative pain relief, without an increase in perioperative bleeding.^[25] Moiniche *et al.*^[26] analyzed 25 studies in their quantitative systematic review and concluded that although there is some evidence of an increased risk of re-operation because of bleeding with NSAIDs, the evidence is equivocal and the risk-benefit ratio is not straight forward.

Moreover, Krishna *et al.*^[27] after their meta-analysis including 1368 patients to determine the risk of post-operative hemorrhage associated with the administration of NSAIDs after tonsillectomy reported that the incidence of the post-operative bleeding was not affected by NSAID consumption. In the current study, patients were observed for perioperative bleeding, and it was found that there was no significant bleeding in excess of usual as assessed by the ENT surgeons.

In agreement with these results, several studies used lornoxicam without any evidence of major perioperative bleeding.^[3,7,8,10,14] Lornoxicam has a more potent anti-inflammatory and analgesic effect than other oxycams in addition to a shorter plasma half-life (approximately 4 h), which decreases the incidence of side-effects in comparison with other drugs with long plasma half-lives,^[6]

and this explained that lornoxicam was well tolerated with less adverse effects. In accordance with this finding, Norholt *et al.*^[28] reported that lornoxicam appeared to possess a higher benefit-risk ratio compared with morphine in terms of common acute adverse events. The most frequent side-effects were nausea and vomiting in the placebo group, which may be attributed to a higher consumption of opioids in the post-operative period; consequently, both lornoxicam and tramadol appear to be more acceptable to ENT surgical patients compared with the traditional opioids regarding the side-effect profile.

Limitation of the Study

The current study assessed the perioperative bleeding subjectively without the use of specific platelet function assessment tests.

CONCLUSION

Tramadol 1 mg/kg was comparable to lornoxicam 8 mg for post-operative pain relief in patients undergoing ENT surgical procedures. Both drugs helped to reduce the post-operative opioid requirement and, consequently, minimized the related adverse effects of the opioids.

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How to cite this article: Abdelhalim AA, Al harethy S, Moustafa M. Lornoxicam versus tramadol for post-operative pain relief in patients undergoing ENT procedures. *Saudi J Anaesth* 2014;8:38-44.
Source of Support: Nil, **Conflict of Interest:** None declared.